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(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(i) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55072, Nov. 24, 1992]

§ 31.14 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 31 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 31 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 31.1, 31.2, 31.3, 31.4, 31.9, 31.13, and 31.14.

[57 FR 55073, Nov. 24, 1992]

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

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AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

SOURCE: 30 FR 8192, June 26, 1965, unless otherwise noted.

§ 32.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially

transfer items containing byproduct material for sale or distribution to:

(1) Persons exempted from the licensing requirements of part 30 of this chapter, or

(2) Persons generally licensed under part 31 or 35 of this chapter.

This part also prescribes certain regulations governing holders of these licenses. In addition, this part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of the licensee or another and regulations governing holders of such licenses. Further, this part describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed source or devices containing sealed sources which are to be used by persons specifically licensed under part 30 of this chapter or equivalent regulations of an Agreement State.

(b) The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of part 30 of this chapter apply to applications, licenses and certificates of registration subject to this part.

[30 FR 8192, June 26, 1965, as amended at 52 FR 27786, July 24, 1987; 63 FR 1896, Jan. 13, 1998]

§ 32.2 Definitions.

As used in this part:

(a) *Dose commitment* means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

(b) *Lot Tolerance Percent Defective* means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

[34 FR 6653, Apr. 18, 1969, as amended at 39 FR 22129, June 20, 1974]

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§ 32.3 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy of a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[53 FR 19246, May 27, 1988]

§ 32.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0001.

(b) The approved information collection requirements contained in this part appear in §§ 32.11, 32.12, 32.14, 32.15, 32.16, 32.17, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, and 32.210.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

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(1) In § 32.11, NRC Form 313 is approved under control number 3150-0120.

(2) [Reserved]

[49 FR 19625, May 9, 1984, as amended at 59 FR 61780, Dec. 2, 1994; 62 FR 52186, Oct. 6, 1997; 62 FR 63640, Dec. 2, 1997]

Subpart A—Exempt Concentrations and Items

§ 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.

An application for a specific license on Form NRC-313 authorizing the introduction of byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the byproduct material will be approved if the applicant:

(a) Satisfies the general requirements specified in § 30.33 of this chapter;

(b) Provides a description of the product or material into which the byproduct material will be introduced, intended use of the byproduct material and the product or material into which it is introduced, method of introduction, initial concentration of the byproduct material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioisotopes in the product or material at the time of transfer; and

(c) Provides reasonable assurance that the concentrations of byproduct material at the time of transfer will not exceed the concentrations in § 30.70 of this chapter, that reconcentration of the byproduct material in concentrations exceeding those in § 30.70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or

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product designed for ingestion or inhalation by, or application to, a human being.

[30 FR 8192, June 26, 1965, as amended at 49 FR 19625, May 9, 1984]

§ 32.12 Same: Records and material transfer reports.

(a) Each person licensed under § 32.11 shall maintain records of transfer of material and file a report with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter. A copy of the report must be sent to the appropriate NRC Regional Office listed in appendix D to part 20 of this chapter.

(b) The report must identify the:

(1) Type and quantity of each product or material into which byproduct material has been introduced during the reporting period;

(2) Name and address of the person who owned or possessed the product or material, into which byproduct material has been introduced, at the time of introduction;

(3) The type and quantity of radionuclide introduced into each product or material; and

(4) The initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee.

(c) The licensee shall file the report within 30 days following:

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under § 30.37; or

(3) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized under the license issued under § 32.11.

(d) The report must cover the period between the filing of the preceding report and the occurrence specified in paragraphs (c) (1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.11 during the reporting period, the report shall so indicate.

(e) The licensee shall maintain the record of a transfer for a period of one

year after the event is included in a report to the Commission.

[48 FR 12333, Mar. 24, 1983; 48 FR 14863, Apr. 6, 1983, as amended at 68 FR 58804, Oct. 10, 2003]

§ 32.13 Same: Prohibition of introduction.

No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under § 30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued pursuant to § 32.11 or the general license provided in § 150.20 of this chapter.

[30 FR 8192, June 26, 1965]

§ 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.

An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in § 30.15 of this chapter or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to § 30.15 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of byproduct material in each product;

(2) Details of construction and design of each product;

(3) The method of containment or binding of the byproduct material in the product;

(4) Procedures for and results of prototype testing to demonstrate that the material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) Quality control procedures to be followed in the fabrication of production lots of the product and the quality

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control standards the product will be required to meet;

(6) The proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product;

(7) For products for which limits on levels of radiation are specified in § 30.15 of this chapter, the radiation level and the method of measurement;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the product.

(c) Each product will contain no more than the quantity of byproduct material specified for that product in § 30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in § 30.15 of this chapter.

(d) The Commission determines that:

(1) The byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

(2) For automobile lock illuminators, the product has been subjected to and meets the requirements of the prototype tests prescribed by § 32.40, schedule A.

[31 FR 5316, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 43 FR 6922, Feb. 17, 1978; 63 FR 32971, June 17, 1998]

§ 32.15 Same: Quality assurance, prohibition of transfer, and labeling.

(a) Each person licensed under § 32.14 shall:

(1) Maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product;

(2) Subject inspection lots to such testing as may be required as a condition of the license issued under § 32.14 taking a random sample of the size required by the tables in § 32.110, and for Lot Tolerance Percent Defective of 5.0 percent, accept or reject inspection lots in accordance with the directions of § 32.110; and

(3) Visually inspect each unit, except electron tubes containing byproduct material, in inspection lots. Any unit which has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit.

(b) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (a)(2) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that the operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(c) No person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an Agreement State:

(1) Any part or product which has been tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective units have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (b) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14.

(d) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

[31 FR 5317, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 39 FR 22129, June 20, 1974; 43 FR 6922, Feb. 17, 1978]

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§ 32.16 Certain items containing by-product material: Records and reports of transfer.

(a) Each person licensed under § 32.14 or § 32.17 shall maintain records of all transfers of nuclear material and file a report with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, with a copy to the appropriate NRC Regional Office listed in appendix D to part 20 of this chapter.

(b) The report must include the following information on items transferred to other persons for use under § 30.15 or § 30.16 of this chapter or equivalent regulations of an Agreement State:

(1) A description or identification of the type of each product;

(2) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred during the reporting period.

(c) The licensee shall file the report within 30 days after:

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under § 30.37; or

(3) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized under the license issued under § 32.14 or § 32.17.

(d) The report must cover the period between the filing of the preceding report and the occurrence specified in paragraphs (c) (1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.14 or § 32.17 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

[48 FR 12333, Mar. 24, 1983; 48 FR 23383, May 25, 1983, as amended at 68 FR 58804, Oct. 10, 2003]

§ 32.17 Resins containing scandium-46 and designed for sand-consolidation in oil wells: Requirements for license to manufacture, or initially transfer for sale or distribution.

An application for a specific license to manufacture, or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use pursuant to § 30.16 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The product is designed to be used only for sand-consolidation in oil wells;

(c) The applicant submits the following information:

(1) The general description of the product to be manufactured or initially transferred.

(2) A description of control procedures to be used to assure that the concentration of scandium-46 in the final product at the time of distribution will not exceed 1.4×10^{-3} microcurie/milliliter.

(d) Each container of such product will bear a durable, legible label approved by the Commission, which contains the following information:

(1) The product name;

(2) A statement that the product contains radioactive scandium and is designed and manufactured only for sand-consolidation in oil wells;

(3) Instructions necessary for proper use; and

(4) The manufacturer's name.

[32 FR 4241, Mar. 18, 1967, as amended by 38 FR 29314, Oct. 24, 1973; 43 FR 6922, Feb. 17, 1978]

§ 32.18 Manufacture, distribution and transfer of exempt quantities of by-product material: Requirements for license.

An application for a specific license to manufacture, process, produce, package, repack, or transfer quantities of byproduct material for commercial distribution to persons exempt pursuant to § 30.18 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however*, That the requirements of § 30.33(a) (2) and (3)

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of this chapter do not apply to an application for a license to transfer byproduct material manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(b) The byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(c) The byproduct material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(d) The applicant submits copies of prototype labels and brochures and the Commission approves such labels and brochures.

[35 FR 6428, Apr. 22, 1970, as amended at 43 FR 6922, Feb. 17, 1978]

§ 32.19 Same: Conditions of licenses.

Each license issued under § 32.18 is subject to the following conditions:

(a) No more than 10 exempt quantities set forth in § 30.71, Schedule B of this chapter shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity.

(b) Each quantity of byproduct material set forth in § 30.71, Schedule B of this chapter shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to § 30.18 of this chapter. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(c) The immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope

and the quantity of radioactivity, and (2) bears the words “Radioactive Material.”

(d) In addition to the labeling information required by paragraph (c) of this section, the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) bear the words “Radioactive Material—Not for Human Use—Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited—Exempt Quantities Should Not be Combined”; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

[35 FR 6428, Apr. 22, 1970]

§ 32.20 Same: Records and material transfer reports.

(a) Each person licensed under § 32.18 of this part shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds and quantities of byproduct material transferred. The licensee shall maintain the record of a transfer for a period of one year after the event is included in a summary report to the Commission.

(b) The licensee shall file a summary report stating the total quantity of each isotope transferred under the specific license with the Director of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, with a copy to the appropriate NRC Regional Office listed in appendix D to part 20 of this chapter.

(c) The licensee shall file the summary report within 30 days following:

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under § 30.37; or

(3) Notifying the Commission under § 30.34(f) of the licensee's decision to

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permanently discontinue activities authorized under the license issued under § 32.18.

(d) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraph (c) (1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.18 during the reporting period, the report must so indicate.

[48 FR 12333, Mar. 24, 1983, as amended at 68 FR 58804, Oct. 10, 2003]

§ 32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for “in vivo” diagnostic use for humans to persons exempt from licensing; Requirements for a license.

(a) An application for a specific license to manufacture, prepare, process, produce, package, repack, or transfer for commercial distribution capsules containing 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for “in vivo” diagnostic use, to persons exempt from licensing under § 30.21 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter, provided that the requirements of § 30.33(a) (2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(2) The applicant meets the requirements under § 32.72(a)(2) of this part;

(3) The applicant provides evidence that each capsule contains 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

(4) The carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this section) or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

(5) The carbon-14 urea is in the form of a capsule, identified as radioactive, and to be used for its radioactive prop-

erties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(6) The applicant submits copies of prototype labels and brochures and the NRC approves these labels and brochures.

(b) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing drugs.

[62 FR 63640, Dec. 2, 1997, as amended at 66 FR 64738, Dec. 14, 2001]

§ 32.21a Same: Conditions of license.

Each license issued under § 32.21 of this part is subject to the following conditions:

(a) The immediate container of the capsule(s) must bear a durable, legible label which:

(1) Identifies the radioisotope, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date; and

(2) Bears the words “Radioactive Material.”

(b) In addition to the labeling information required by paragraph (a) of this section, the label affixed to the immediate container, or an accompanying brochure also must:

(1) State that the contents are exempt from NRC or Agreement State licensing requirements; and

(2) Bears the words “Radioactive Material. For ‘In Vivo’ Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects and Must Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals, or into Products Manufactured for Commercial Distribution. This Material May Be Disposed of in Ordinary Trash.”

[62 FR 63640, Dec. 2, 1997]

§ 32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.

(a) An application for a specific license to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to initially transfer such products for use pursuant to § 30.19

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of this chapter or equivalent regulations of an Agreement State, will be approved if:

(1) The applicant satisfies the general requirements specified in §30.33 of this chapter: *Provided, however*, That the requirements of §30.33(a) (2) and (3) do not apply to an application for a license to transfer tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, or produced pursuant to a license issued by an Agreement State.

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the self-luminous product to demonstrate that the product will meet the safety criteria set forth in §32.23. The information should include:

(i) A description of the product and its intended use or uses.

(ii) The type and quantity of byproduct material in each unit.

(iii) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

(iv) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (a)(2)(iii) and (xii) of this section.

(v) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product.

(vi) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

(vii) Degree of access of human beings to the product during normal handling and use.

(viii) Total quantity of byproduct material expected to be distributed in the product annually.

(ix) The expected useful life of the product.

(x) The proposed method of labeling or marking each unit with identifica-

tion of the manufacturer or initial transferor of the product and the byproduct material in the product.

(xi) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

(xii) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(xiii) The estimated external radiation doses and dose commitments relevant to the safety criteria in §32.23 and the basis for such estimates.

(xiv) A determination that the probabilities with respect to the doses referred to in §32.23(d) meet the criteria of that paragraph.

(xv) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

(xvi) Any additional information, including experimental studies and tests, required by the Commission.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Commission may deny an application for a specific license under this section if the end uses of the product cannot be reasonably foreseen.

[34 FR 9026, June 6, 1969, as amended at 43 FR 6923, Feb. 17, 1978]

§ 32.23 Same: Safety criteria.

An applicant for a license under §32.22 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the

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appropriate organ as specified in Column I of the table in § 32.24 of this part.

(b) In normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column II of the table in § 32.24.

(c) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(d)¹In use and disposal of a single exempt unit, or in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.24, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in § 32.24.

¹It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low—not more than one such failure per year for each 10,000 exempt units distributed.

Negligible—not more than one such failure per year for each 1 million exempt units distributed.

[34 FR 9027, June 6, 1969]

§ 32.24 Same: Table of organ doses.

Part of body	Column I (rem)	Column II (rem)	Column III (rem)	Column IV (rem)
Whole body; head and trunk: active blood-forming organs; gonads: or lens of eye	0.001	0.01	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.015	0.15	7.5	200
Other organs	0.003	0.03	1.5	50

[34 FR 9329, June 13, 1969]

§ 32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and reports of transfer.

Each person licensed under § 32.22 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the product and the byproduct material in the product can be identified; and

(c) Maintain records and file reports with the Director of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a), with copies to the appropriate NRC Regional Office listed in appendix D to part 20 of this chapter.

(1) The report must include the following information on products transferred to other persons for use under § 30.19 of this chapter or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product;

(ii) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(iii) The number of units of each type of product transferred during the reporting period.

(2) The licensee shall file the report within 30 days following:

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(i) Five years after filing the preceding report; or

(ii) Filing an application for renewal of the license under § 30.37; or

(iii) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized under the license issued under § 32.22.

(3) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraphs (c)(2)(i), (ii), or (iii) of this section. If no transfers of byproduct material have been made under § 32.22 during the reporting period, the report must so indicate.

(4) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

[34 FR 9027, June 6, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 48 FR 12334, Mar. 24, 1983; 68 FR 58804, Oct. 10, 2003]

§ 32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect life or property from fires and airborne hazards, or to initially transfer such products for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however*, That the requirements of § 30.33(a) (2) and (3) do not apply to an application for a license to transfer byproduct material in gas and aerosol detectors manufactured, processed or produced pursuant to a license issued by an Agreement State.

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the gas and aerosol detector to demonstrate that the product will meet the safety

criteria set forth in § 32.27. The information should include:

(1) A description of the product and its intended use or uses;

(2) The type and quantity of byproduct material in each unit;

(3) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product;

(4) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (b) (3) and (12) of this section;

(5) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product;

(6) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement;

(7) Degree of access of human beings to the product during normal handling and use;

(8) Total quantity of byproduct material expected to be distributed in the product annually;

(9) The expected useful life of the product;

(10) The proposed methods of labeling or marking the detector and its point-of-sale package to satisfy the requirements of § 32.29(b);

(11) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product;

(12) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features;

(13) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.27 and the basis for such estimates;

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(14) A determination that the probabilities with respect to the doses referred to in § 32.27(c) meet the criteria of that paragraph;

(15) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet; and

(16) Any additional information, including experimental studies and tests, required by the Commission.

[34 FR 6653, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980]

§ 32.27 Same: Safety criteria.

An applicant for a license under § 32.26 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in § 32.28.

(b) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(c) In use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in § 32.28, and

the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.28.¹

[34 FR 6654, Apr. 18, 1969]

§ 32.28 Same: Table of organ doses.

Part of body	Column I (rem)	Column II (rem)	Column III (rem)
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.005	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter ..	0.075	7.5	200
Other organs	0.015	1.5	50

[34 FR 6654, Apr. 18, 1969]

§ 32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and reports of transfer.

Each person licensed under § 32.26 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each detector and its point-of-sale package so that:

(1) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(i) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(ii) The name of the radionuclide and quantity of activity; and

¹It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low—not more than one such failure per year for each 10,000 exempt units distributed.

Negligible—not more than one such failure per year for each one million exempt units distributed.

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(iii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State.

(2) The labeling or marking specified in paragraph (b)(1) of this section is located where its will be readily visible when the detector is removed from its mounting.

(3) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(i) The name of the radionuclide and quantity of activity;

(ii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement:

THIS DETECTOR CONTAINS RADIO-ACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

(4) Each detector and point-of-sale package is provided with such other information as may be required by the Commission; and

(c) Maintain records and file a report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with copies to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter.

(1) The report must include the following information on products transferred to other persons for use under § 30.20 of this chapter or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product;

(ii) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(iii) The number of units of each type of product transferred during the reporting period.

(2) The licensee shall file the report within 30 days following:

(i) Five years after filing the preceding report; or

(ii) Filing an application for renewal of the license under § 30.37; or

(iii) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized pursuant to the license issued under § 32.26.

(3) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraphs (c)(2) (i), (ii), or (iii) of this section. If no transfers of byproduct material have been made under § 32.26 during the reporting period, the report must so indicate.

(4) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

[34 FR 6654, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980; 48 FR 12334, Mar. 24, 1983]

§ 32.40 Schedule A—Prototype tests for automobile lock illuminators.

An applicant for a license pursuant to § 32.14 to install lock illuminators into automobile locks, or to initially transfer lock illuminators in automobile locks for use pursuant to § 30.15 of this chapter shall conduct the following prototype tests on each of five prototype devices, consisting of the automobile lock with the installed illuminator in the following order:

(a) The device shall be subjected to 100 hours of accelerated weathering in a suitable weathering machine which simulates the most severe conditions of normal use;

(b) The device shall be dropped upon a concrete or iron surface in a 3-foot free gravitational fall, or shall be subjected to an equivalent treatment in a test device simulating such a fall. The drop test shall be repeated 100 times from random orientations;

(c) The device shall be attached to a vibratory fixture and vibrated at a rate of not less than 26 cycles per second and a vibration acceleration of not less than 2 G for a period of not less than 1 hour;

(d) On completion of the foregoing tests, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry into the lock illuminator. Absolute pressure of the air above the water

shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any evidence of bubbles emanating from within the lock illuminator, or water entering the lock illuminator, shall be considered leakage;

(e) After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of tritium or promethium-147. Any evidence of damage to or failure of any device which could affect the containment of the tritium or promethium-147 in such devices shall be cause for rejection of the design on which such prototype devices were constructed or manufactured if the damage or failure is attributable to design defect. Loss of tritium or promethium-147 from each tested device shall be measured both by sampling the immersion test water used in paragraph (d) of this section and by wiping with filter paper the entire accessible area of the lock illuminator. Measurements of tritium or promethium-147 shall be made in an apparatus calibrated to measure tritium or promethium-147, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium-147 in the device is found in the immersion test water of the test in paragraph (d) of this section, or if more than 2,200 disintegrations per minute of tritium or promethium-147 on the filter paper is measured after any of the tests in paragraphs (a) to (d) of this section the device shall be rejected.

[30 FR 8192, June 26, 1965, as amended at 31 FR 5317, Apr. 2, 1966; 43 FR 6923, Feb. 17, 1978]

Subpart B—Generally Licensed Items

§ 32.51 Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer.

(a) An application for a specific license to manufacture, or initially transfer devices containing byproduct material to persons generally licensed under § 31.5 of this chapter or equivalent

regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements of § 30.33 of this chapter;

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(i) The device can be safely operated by persons not having training in radiological protection;

(ii) Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in 1 year a dose in excess of 10 percent of the annual limits specified in § 20.1201(a) of this chapter; and

(iii) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in § 32.24.

(3) Each device bears a durable, legible, clearly visible label or labels approved by the Commission which contain in a clearly identified and separate statement:

(i) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(ii) The requirements, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(iii) The information called for in the following statement in the same or substantially similar form:¹

¹Devices licensed under § 32.51 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

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The receipt, possession, use, and transfer of this device Model _____², Serial No. _____², are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—RADIOACTIVE MATERIAL

(Name of manufacturer, or initial transferor)²

(4) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, “Caution-Radioactive Material,” the radiation symbol described in § 20.1901 of this chapter, and the name of the manufacturer or initial distributor.

(5) Each device meeting the criteria of § 31.5(c)(13)(i) of this chapter, bears a permanent (*e.g.*, embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, “Caution-Radioactive Material,” and, if practicable, the radiation symbol described in § 20.1901 of this chapter.

(b) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Commission

will consider information which includes, but is not limited to:

- (1) Primary containment (source capsule);
- (2) Protection of primary containment;
- (3) Method of sealing containment;
- (4) Containment construction materials;
- (5) Form of contained radioactive material;
- (6) Maximum temperature withstood during prototype tests;
- (7) Maximum pressure withstood during prototype tests;
- (8) Maximum quantity of contained radioactive material;
- (9) Radiotoxicity of contained radioactive material; and
- (10) Operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant desires that the general licensee under § 31.5 of this chapter, or under equivalent regulations of an Agreement State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the bases for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the annual limits specified in § 20.1201(a) of this chapter.

[39 FR 43533, Dec. 16, 1974, as amended at 40 FR 8785, Mar. 3, 1975; 42 FR 25721, May 19, 1977; 43 FR 6923, Feb. 17, 1978; 58 FR 67660, Dec. 22, 1993; 59 FR 5520, Feb. 7, 1994; 65 FR 79189, Dec. 18, 2000]

§ 32.51a Same: Conditions of licenses.

(a) If a device containing byproduct material is to be transferred for use under the general license contained in § 31.5 of this chapter, each person that

²The model, serial number, and the name of the manufacturer, or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

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is licensed under §32.51 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes—

(1) A copy of the general license contained in §31.5 of this chapter; if paragraphs (c)(2) through (4) or (c)(13) of §31.5 do not apply to the particular device, those paragraphs may be omitted.

(2) A copy of §§31.2, 30.51, 20.2201, and 20.2202 of this chapter;

(3) A list of the services that can only be performed by a specific licensee;

(4) Information on acceptable disposal options including estimated costs of disposal; and

(5) An indication that NRC's policy is to issue high civil penalties for improper disposal.

(b) If byproduct material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under §32.51 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes—

(1) A copy of the Agreement State's regulations equivalent to §§31.5, 31.2, 30.51, 20.2201, and 20.2202 of this chapter or a copy of §§31.5, 31.2, 30.51, 20.2201, and 20.2202 of this chapter. If a copy of the NRC regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

(2) A list of the services that can only be performed by a specific licensee;

(3) Information on acceptable disposal options including estimated costs of disposal; and

(4) The name or title, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained.

(c) An alternative approach to informing customers may be proposed by the licensee for approval by the Commission.

(d) Each device that is transferred after February 19, 2002 must meet the labeling requirements in §32.51(a)(3) through (5).

(e) If a notification of bankruptcy has been made under §30.34(h) or the license is to be terminated, each person licensed under §32.51 shall provide, upon request, to the NRC and to any appropriate Agreement State, records of final disposition required under §32.52(c).

[65 FR 79189, Dec. 18, 2000; 65 FR 80991, Dec. 22, 2000]

§ 32.52 Same: material transfer reports and records.

Each person licensed under §32.51 to initially transfer devices to generally licensed persons shall comply with the requirements of this section.

(a) The person shall report to the Director of Nuclear Material Safety and Safeguards, ATTN: GLTS, by an appropriate method listed in §30.6(a), all transfers of such devices to persons for use under the general license in §31.5 of this chapter and all receipts of devices from persons licensed under §31.5 of this chapter. The report must be submitted on a quarterly basis on Form 653—"Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes—

(i) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(ii) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of byproduct material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(3) For devices received from a §31.5 general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(4) If the licensee makes changes to a device possessed by a §31.5 general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(5) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(6) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(7) If no transfers have been made to or from persons generally licensed under §31.5 of this chapter during the reporting period, the report must so indicate.

(b) The person shall report all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to §31.5 of this chapter and all receipts of devices from general licensees in the Agreement State's jurisdiction to the

responsible Agreement State agency. The report must be submitted on Form 653—"Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes—

(i) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(ii) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of byproduct material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(3) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(4) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(5) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(6) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(7) If no transfers have been made to or from a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency.

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

[65 FR 79189, Dec. 18, 2000, as amended at 68 FR 58805, Oct. 10, 2003]

§ 32.53 Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.

An application for a specific license to manufacture, assemble, repair or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under § 31.7 of this chapter, will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;

(2) Details of construction and design;

(3) Details of the method of binding or containing the tritium or promethium-147;

(4) Procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

(5) Any quality control procedures proposed as alternatives to those prescribed by § 32.55;

(6) Any additional information, including experimental studies and tests, required by the Commission to facili-

tate a determination of the safety of the device.

(c) Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

(d) The Commission determines that:

(1) The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(2) The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;

(3) The device is so designed that it cannot easily be disassembled; and

(4) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.101, Schedule B, of this part.

[30 FR 8192, June 26, 1965, as amended at 33 FR 6463, Apr. 27, 1968; 43 FR 6923, Feb. 17, 1978]

§ 32.54 Same: Labeling of devices.

(a) A person licensed under § 32.53 to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under § 31.7 of this chapter shall, except as provided in paragraph (b) of this section, affix to each device a label containing the radiation symbol prescribed by § 20.1901 of this chapter, such other information as may be required by the Commission including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement:¹

The receipt, possession, use, and transfer of this device, Model* _____, Serial No.* _____, containing _____ (Identity and quantity of radioactive material) are

¹Devices licensed under § 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

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subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL

(Name of manufacturer, assembler, or initial transferor.)*

*The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(b) If the Commission determines that it is not feasible to affix a label to the device containing all the information called for in paragraph (a) of this section, it may waive the requirements of that paragraph and require in lieu thereof that:

(1) A label be affixed to the device identifying:

(i) The manufacturer, assembler, or initial transferor; and

(ii) The type of radioactive material; and

(2) A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(i) The name of the manufacturer, assembler, or initial transferor,

(ii) The type and quantity of radioactive material,

(iii) The model number,

(iv) A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the U.S. NRC or of an Agreement State, and

(v) Such other information as may be required by the Commission, including disposal instructions when appropriate.

[33 FR 16331, Nov. 7, 1968, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6923, Feb. 17, 1978; 63 FR 39483, July 23, 1998]

§ 32.55 Same: Quality assurance; prohibition of transfer.

(a) Each person licensed under § 32.53 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the tritium or promethium-147.

(b) Each person licensed under § 32.53 shall take a random sample of the size

required by the table in § 32.110 for Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and shall subject each unit in the sample to the following tests:

(1) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks as evidenced by bubbles emanating from within the device, or water entering the device, shall be considered as a defective unit.

(2) The immersion test water from the preceding test in paragraph (b)(1) of this section shall be measured for tritium or promethium-147 content by an apparatus that has been calibrated to measure tritium or promethium-147, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium-147 in any device is found to have leaked into the immersion test water, the leaking device shall be considered as a defective unit.

(3) The levels of radiation from each device containing promethium-147 shall be measured. Any device which has a radiation level in excess of 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, shall be considered as a defective unit.

(c) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (b) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that:

(1) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of tritium or promethium 147 in any 24-hour period; and

(2) The operating characteristic curve or confidence interval estimate for the alternative procedures provides

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a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of this chapter:

(1) Any luminous safety device which has been tested and found defective under the criteria and procedures specified in this section, unless the defective units have been repaired or reworked and have then met the tests set out in paragraph (b) of this section; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (c) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in paragraph (b) of this section.

[30 FR 8192, June 26, 1965, as amended at 39 FR 22129, June 20, 1974; 39 FR 26397, July 19, 1974]

§ 32.56 Same: Material transfer reports.

Each person licensed under § 32.53 shall file an annual report with the Director of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter, which report must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under § 31.7 of this chapter. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter.

[60 FR 3737, Jan. 19, 1995, as amended at 68 FR 58805, Oct. 10, 2003]

§ 32.57 Calibration or reference sources containing americium-241: Requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

(a) The applicant satisfies the general requirements of § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of americium-241 in the source;

(2) Details of construction and design;

(3) Details of the method of incorporation and binding of the americium-241 in the source;

(4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241, to demonstrate that the americium-241 contained in each source will not be released or be removed from the source under normal conditions of use;

(5) Details of quality control procedures to be followed in manufacture of the source;

(6) Description of labeling to be affixed to the source or the storage container for the source;

(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(c) Each source will contain no more than 5 microcuries of americium-241.

(d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241, that:

(1) The method of incorporation and binding of the americium-241 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(2) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.102, Schedule C, of this part.

[30 FR 8192, June 26, 1965, as amended at 43 FR 6923, Feb. 17, 1978]

§ 32.58 Same: Labeling of devices.

Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information

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relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:¹

The receipt, possession, use and transfer of this source, Model ____-, Serial No. ____-, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—
THIS SOURCE CONTAINS AMERICIUM-
241. DO NOT TOUCH RADIOACTIVE POR-
TION OF THIS SOURCE.

Name of manufacturer or initial transferor)

(Sec. 161, as amended, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); sec. 201, as amended, Pub. L. 93-438, 88 Stat. 1243 (42 U.S.C. 5841))

[30 FR 8192, June 26, 1965, as amended at 40 FR 8786, Mar. 3, 1975; 43 FR 6923, Feb. 17, 1978]

§ 32.59 Same: Leak testing of each source.

Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 0.1 microcurie of americium-241 prior to transferring the source to a general licensee under § 31.8 of this chapter. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 microcurie of americium-241. If any such test discloses more than 0.005 microcurie of radioactive material, the source shall be deemed to be leaking or losing americium-241 and shall not be transferred to a general licensee under § 31.8 of this chapter.

[30 FR 8192, June 26, 1965]

¹Sources licensed under § 32.57 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

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§ 32.60 [Reserved]

§ 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under § 31.10 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of strontium-90 in the device;

(2) Details of construction and design of the source of radiation and its shielding;

(3) Radiation profile of a prototype device;

(4) Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

(5) Details of quality control procedures to be followed in manufacture of the device;

(6) Description of labeling to be affixed to the device;

(7) Instructions for handling and installation of the device;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device;

(c) Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form;

(d) Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by § 20.1901(a) of this chapter, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer

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or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices;

(e) The Commission determines that:

(1) The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(2) The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;

(3) The device is so designed that it cannot be easily disassembled;

(4) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.103; and

(5) Quality control procedures have been established to satisfy the requirements of § 32.62.

[30 FR 9905, Aug. 10, 1965, as amended at 43 FR 6923, Feb. 17, 1978; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§ 32.62 Same: Quality assurance; prohibition of transfer.

(a) Each person licensed under § 32.61 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(b) Each person licensed under § 32.61 shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

(c) Each person licensed under § 32.61 shall take a random sample of the size required by the table in § 32.110 for Lot Tolerance Percent Defective of 5.0 per-

cent from each inspection lot, and shall subject each unit in the sample to the following tests:

(1) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks, as evidenced by physical contact between the water and the strontium-90, shall be considered as a defective unit.

(2) The immersion test water from the preceding test in paragraph (c)(1) of this section shall be measured for radioactive material. If the amount of radioactive material in the immersion test water is greater than 0.1 percent of the original amount of strontium-90 in any device, the device shall be considered as a defective unit.

(d) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (c) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that:

(1) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of strontium-90 in any 24-hour period; and

(2) The operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(e) No person licensed under § 32.61 shall transfer to persons generally licensed under § 31.10 of this chapter:

(1) Any device which has been tested and found defective under the criteria and procedures specified in this § 32.62 unless the defective units have been repaired or reworked and then met the tests set out in paragraph (c) of this section; or

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(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (d) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in paragraph (c) of this section.

[30 FR 9905, Aug. 10, 1965, as amended at 39 FR 22130, June 20, 1974; 39 FR 26397, July 19, 1974; 43 FR 6923, Feb. 17, 1978]

§ 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.

An application for a specific license to manufacture or distribute byproduct material for use under the general license of § 31.11 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter.

(b) The byproduct material is to be prepared for distribution in prepackaged units of:

(1) Iodine-125 in units not exceeding 10 microcuries each.

(2) Iodine-131 in units not exceeding 10 microcuries each.

(3) Carbon-14 in units not exceeding 10 microcuries each.

(4) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.

(5) Iron-59 in units not exceeding 20 microcuries each.

(6) Selenium-75 in units not exceeding 10 microcuries each.

(7) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(c) Each prepackaged unit bears a durable, clearly visible label:

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-131, iodine-125, selenium-75, or carbon-14; 50 microcuries of hydrogen-3 (tritium); or 20 microcuries of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and

(2) Displaying the radiation caution symbol described in § 20.1901(a) of this chapter and the words, "Caution, Ra-

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dioactive Material", and "Not for Internal or External Use in Humans or Animals."

(d) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:¹

The radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of Manufacturer)

(e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such byproduct material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in § 20.2001.

[33 FR 16553, Nov. 14, 1968, as amended at 38 FR 34110, Dec. 11, 1973; 39 FR 26148, July 17, 1974; 40 FR 8786, Mar. 3, 1975; 42 FR 21604, Apr. 28, 1977; 42 FR 26987, May 26, 1977; 44 FR 50325, Aug. 28, 1979; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized

¹Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

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pursuant to part 35 of this chapter will be approved if:

(1) The applicant satisfies the general requirements specified in 10 CFR 30.33;

(2) The applicant submits evidence that the applicant is at least one of the following:

(i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

(ii) Registered or licensed with a state agency as a drug manufacturer;

(iii) Licensed as a pharmacy by a State Board of Pharmacy; or

(iv) Operating as a nuclear pharmacy within a Federal medical institution.

(3) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(4) The applicant satisfies the following labeling requirements:

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(ii) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee described by paragraph (a)(2)(iii) or (iv) of this section:

(1) May prepare radioactive drugs for medical use, as defined in 10 CFR 35.2,

provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraphs (b)(2) and (b)(4) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.27.

(2) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in 10 CFR 35.2,

(ii) This individual meets the requirements specified in 10 CFR 35.55(b) or, prior to October 25, 2004, 10 CFR 35.980(b) and 35.59 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (b)(4) of this section.

(3) The actions authorized in paragraphs (b)(1) and (b)(2) of this section are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist (as defined in 10 CFR 35.2) as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the Commission under this part.

(5) Shall provide to the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

(d) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

[59 FR 61780, Dec. 2, 1994; 59 FR 65244, Dec. 19, 1994, as amended at 60 FR 324, Jan. 4, 1995; 67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002; 67 FR 77652, Dec. 19, 2002]

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to part 35 of this chapter for use as a calibration or reference source or for the uses listed in §§ 35.400, 35.500, and 35.600 of this chapter will be approved if:

(1) The applicant satisfies the general requirements in § 30.33 of this chapter;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) The byproduct material contained, its chemical and physical form, and amount;

(ii) Details of design and construction of the source or device;

(iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(iv) For devices containing byproduct material, the radiation profile of a prototype device;

(v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(vi) Procedures and standards for calibrating sources and devices;

(vii) Legend and methods for labeling sources and devices as to their radioactive content;

(viii) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device: *Provided*, That instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use byproduct material identified in §§ 35.65, 35.400, 35.500, and 35.600 as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

(b)(1) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(2) In determining the acceptable interval for test of leakage of radioactive material, the Commission will consider information that includes, but is not limited to:

(i) Primary containment (source capsule);

(ii) Protection of primary containment;

(iii) Method of sealing containment;

(iv) Containment construction materials;

- (v) Form of contained radioactive material;
- (vi) Maximum temperature withstood during prototype tests;
- (vii) Maximum pressure withstood during prototype tests;
- (viii) Maximum quantity of contained radioactive material;
- (ix) Radiotoxicity of contained radioactive material;
- (x) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(c) If an application is filed pursuant to paragraph (a) of this section on or before October 15, 1974, for a license to manufacture and distribute a source or device that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such source or device to group licensees until the Commission issues the license or notifies the applicant otherwise.

[39 FR 26149, July 17, 1974, as amended at 51 FR 36967, Oct. 16, 1986; 62 FR 59276, Nov. 3, 1997; 67 FR 20370, Apr. 24, 2002]

§ 32.101 Schedule B—prototype tests for luminous safety devices for use in aircraft.

An applicant for a license pursuant to § 32.53 shall conduct prototype tests on each of five prototype luminous safety devices for use in aircraft as follows:

(a) *Temperature-altitude test.* The device shall be placed in a test chamber as it would be used in service. A temperature-altitude condition schedule shall be followed as outlined in the following steps:

Step 1. The internal temperature of the test chamber shall be reduced to -62°C . (-80°F .) and the device shall be maintained for at least 1 hour at this temperature at atmospheric pressure.

Step 2. The internal temperature of the test chamber shall be raised to -54°C . (-65°F .) and maintained until the temperature of the device has stabilized at -54°C . at atmospheric pressure.

Step 3. The atmospheric pressure of the chamber shall be reduced to 83 millimeters of mercury absolute pressure while the chamber temperature is maintained at -54°C .

Step 4. The internal temperature of the chamber shall be raised to -10°C . ($+14^{\circ}\text{F}$.) and maintained until the temperature of the

device has stabilized at -10°C ., and the internal pressure of the chamber shall then be adjusted to atmospheric pressure. The test chamber door shall then be opened in order that frost will form on the device, and shall remain open until the frost has melted but not long enough to allow the moisture to evaporate. The door shall then be closed.

Step 5. The internal temperature of the chamber shall be raised to $+85^{\circ}\text{C}$. (185°F .) at atmospheric pressure. The temperature of the device shall be stabilized at $+85^{\circ}\text{C}$. and maintained for 2 hours. The device shall then be visually inspected to determine the extent of any deterioration.

Step 6. The chamber temperature shall be reduced to $+71^{\circ}\text{C}$. (160°F .) at atmospheric pressure. The temperature of the device shall be stabilized at $+71^{\circ}\text{C}$. for a period of 30 minutes.

Step 7. The chamber temperature shall be reduced to $+55^{\circ}\text{C}$. (130°F .) at atmospheric pressure. The temperature of the device shall be stabilized at this temperature for a period of 4 hours.

Step 8. The internal temperature of the chamber shall be reduced to $+30^{\circ}\text{C}$. (86°F .) and the pressure to 138 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 4 hours.

Step 9. The temperature of the test chamber shall be raised to $+35^{\circ}\text{C}$. (95°F .) and the pressure reduced to 83 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 30 minutes.

Step 10. The internal pressure of the chamber shall be maintained at 83 millimeters of mercury absolute pressure and the temperature reduced to $+20^{\circ}\text{C}$. (68°F .) and stabilized. The device shall be maintained under these conditions for a period of 4 hours.

(b) *Vibration tests.* This procedure applies to items of equipment (including vibration isolating assemblies) intended to be mounted directly on the structure of aircraft powered by reciprocating, turbojet, or turbo-propeller engines or to be mounted directly on gas-turbine engines. The device shall be mounted on an apparatus dynamically similar to the most severe conditions likely to be encountered in normal use. At the end of the test period, the device shall be inspected thoroughly for possible damage. Vibration tests shall be conducted under both resonant and cycling conditions according to the following Vibration Test Schedule (Table I):

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VIBRATION TEST SCHEDULE—TABLE I
[Times shown refer to one axis of vibration]

Type	Vibration at room temperature (minutes)	Vibration at 160 °F. (71 °C.) (minutes)	Vibration at –65 °F. (–54 °C.) (minutes)
Resonance	60	15	15
Cycling	60	15	15

(1) *Determination of resonance frequency.* Individual resonance frequency surveys shall be conducted by applying vibration to each device along each of any set of three mutually perpendicular axes and varying the frequency of applied vibration slowly through a range of frequencies from 5 cycles per second to 500 cycles per second with the double amplitude of the vibration not exceeding that shown in Figure 1 for the related frequency.

(2) *Resonance tests.* The device shall be vibrated at the determined resonance frequency for each axis of vibration for the periods and temperature conditions shown in table I and with the applied double amplitude specified in Figure 1 for that resonance frequency. When more than one resonant frequency is encountered with vibration applied along any one axis, the test period may be accomplished at the most severe resonance or the period may be divided among the resonant frequencies, whichever is considered most likely to produce failure. When resonant frequencies are not apparent within the specified frequency range, the specimen shall be vibrated for periods twice as long as those shown for resonance in table I at a frequency of 55 cycles per second and an applied double amplitude of 0.060 inch.

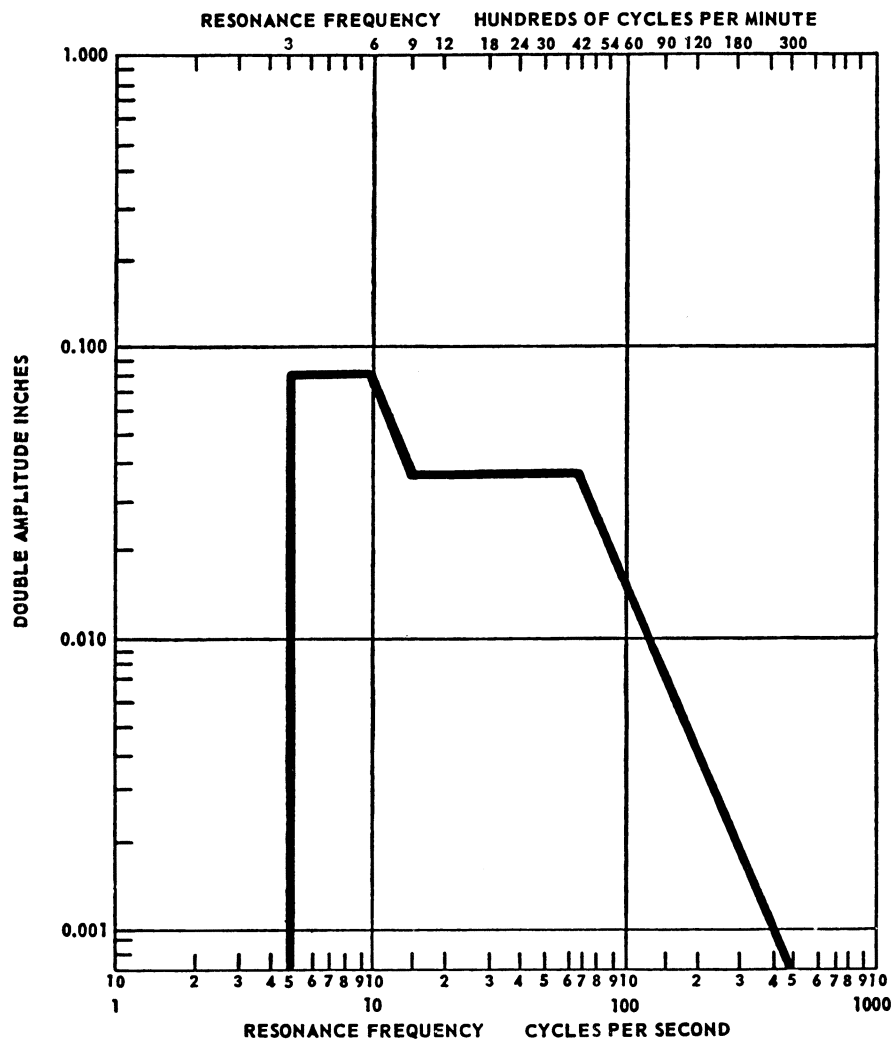


FIGURE 1—Amplitude of vibration at resonance frequency.

(3) *Cycling.* Devices to be mounted only on vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.060 inch and the frequency cycling between 10 and 55 cycles per second in 1-minute cycles for the periods and temperature conditions shown in table I. Devices to be installed in aircraft without vibration isolators

shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.036 inch or an applied acceleration of 10G, whichever is the limiting value, and the frequency cycling between 10 and 500 cycles per second in 15-minute cycles for the periods and temperature conditions shown in table I.

(c) *Accelerated weathering tests.* The device shall be subjected to 100 hours of accelerated weathering in a suitable weathering machine. Panels of Corex D glass shall surround the arc to cut off the ultraviolet radiation below a wavelength of 2,700 angstroms. The light of the carbon arcs shall fall directly on the face of the device. The temperature at the sample shall be maintained at 50 °C. plus or minus 3 °C. Temperature measurements shall be made with a black panel thermometer.

(d) *Shock test.* The device shall be dropped upon a concrete or iron surface in a 3-foot free gravitational fall, or shall be subjected to equivalent treatment in a test device simulating such a free fall. The drop test shall be repeated 100 times from random orientations.

(e) *Hermetic seal and waterproof test.* On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any evidence of bubbles emanating from within the device, or water entering the device, shall be considered leakage.

(f) *Observations.* After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of tritium or promethium-147. Any evidence of damage to or failure of any device which could affect containment of the tritium or promethium-147 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of tritium or promethium-147 from each tested device shall be measured by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The amount of tritium or promethium-147 in the water used in the hermetic seal and waterproof test prescribed by test paragraph (e) of this

section shall also be measured. Measurements shall be made in an apparatus calibrated to measure tritium or promethium-147, as appropriate. The detection on the filter paper of more than 2,200 disintegrations per minute of tritium or promethium-147 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of tritium or promethium-147 in any device shall be cause for rejection of the tested device.

[30 FR 8192, June 26, 1965]

§ 32.102 Schedule C—prototype tests for calibration or reference sources containing americium-241.

An applicant for a license pursuant to § 32.57 shall, for any type of source which is designed to contain more than 0.005 microcurie of americium-241, conduct prototype tests, in the order listed, on each of five prototypes of such source, which contains more than 0.005 microcurie of americium-241, as follows:

(a) *Initial measurement.* The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

(b) *Dry wipe test.* The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

(c) *Wet wipe test.* The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(d) *Water soak test.* The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source

after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(e) *Dry wipe test.* On completion of the preceding test in this section, the dry wipe test described in paragraph (b) of this section shall be repeated.

(f) *Observations.* Removal of more than 0.005 microcurie of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted to the Commission shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

[30 FR 8192, June 26, 1965, as amended at 31 FR 15145, Dec. 2, 1966]

§ 32.103 Schedule D—prototype tests for ice detection devices containing strontium-90.

An applicant for a license pursuant to § 32.61 shall conduct prototype tests on each of five prototype ice detection devices as follows:

(a) *Temperature-altitude test.* The device shall be placed in a test chamber as it would be used in service. A temperature-altitude condition schedule shall be followed as outlined in Step 1 through Step 10 of § 32.101(a).

(b) *Vibration tests.* The device shall be subjected to vibration tests as set forth in § 32.101(b).

(c) *Shock test.* The device shall be subjected to shock test as set forth in § 32.101(d).

(d) *Hermetic seal and waterproof test.* On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any visible evidence of physical contact between the water and the strontium-90 shall be considered leakage.

(e) *Observations.* After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of strontium-90. Any evidence of leakage or damage to or failure of any device which could affect containment of the strontium-90 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of strontium-90 from each tested device shall be measured by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The amount of strontium-90 in the water used in the hermetic seal and waterproof test prescribed in paragraph (d) of this section shall also be measured. The detection on the filter paper of more than 2,200 disintegrations per minute of strontium-90 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of strontium-90 in any device, shall be cause for rejection of the tested device.

[30 FR 9906, Aug. 10, 1965]

Subpart C—Quality Control Sampling Procedures

§ 32.110 Acceptance sampling procedures under certain specific licenses.

(a) A random sample shall be taken from each inspection lot of devices licensed under §§ 32.14, 32.53, or 32.61 of this part for which testing is required pursuant to §§ 32.15, 32.55, or 32.62 in accordance with the appropriate Sampling Table in this section determined by the designated Lot Tolerance Percent Defective. If the number of defectives in the sample does not exceed the acceptance number in the appropriate Sampling Table in this section, the lot shall be accepted. If the number of defectives in the sample exceeds the acceptance number in the appropriate Sampling Table in this section, the entire inspection lot shall be rejected.

(b) Single sampling tables for Lot Tolerance Percent Defective:

(1) Lot Tolerance Percent Defective 0.5 percent:

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Lot size	Sample size	Acceptance No.
1 to 180	All	0
181 to 210	180	0
211 to 250	210	0
251 to 300	240	0
301 to 400	275	0
401 to 500	300	0
501 to 600	320	0
601 to 800	350	0
801 to 1,000	365	0
1,001 to 2,000	410	0
2,001 to 3,000	430	0
3,001 to 4,000	440	0
4,001 to 5,000	445	0
5,001 to 7,000	450	0
7,001 to 10,000	455	0
10,001 to 20,000	460	0
20,001 to 50,000	775	1
50,001 to 100,000	780	1

(2) Lot Tolerance Percent Defective 1.0 percent:

Lot size	Sample size	Acceptance No.
1 to 120	All	0
121 to 150	120	0
151 to 200	140	0
201 to 300	165	0
301 to 400	175	0
401 to 500	180	0
501 to 600	190	0
601 to 800	200	0
801 to 1,000	205	0
1,001 to 3,000	220	0
3,001 to 5,000	225	0
5,001 to 10,000	230	0
10,001 to 100,000	390	1

(3) Lot Tolerance Percent Defective 2.0 percent:

Lot size	Sample size	Acceptance No.
1 to 75	All	0
76 to 100	70	0
101 to 200	85	0
201 to 300	95	0
301 to 400	100	0
401 to 600	105	0
601 to 800	110	0
801 to 4,000	115	0
4,001 to 10,000	195	1
10,001 to 100,000	200	1

(4) Lot Tolerance Percent Defective 3.0 percent:

Lot size	Sample size	Acceptance No.
1 to 40	All	0
41 to 55	40	0
56 to 100	55	0
101 to 200	65	0
201 to 500	70	0
501 to 3,000	75	0
3,001 to 100,000	130	1

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(5) Lot Tolerance Percent Defective 4.0 percent:

Lot size	Sample size	Acceptance No.
1 to 35	All	0
36 to 50	34	0
51 to 100	44	0
101 to 200	50	0
201 to 2,000	55	0
2,001 to 100,000	95	1

(6) Lot Tolerance Percent Defective 5.0 percent:

Lot size	Sample size	Acceptance No.
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2,001 to 100,000	75	1

(7) Lot Tolerance Percent Defective 7.0 percent:

Lot size	Sample size	Acceptance No.
1 to 25	All	0
26 to 50	24	0
51 to 100	28	0
101 to 200	30	0
201 to 300	31	0
301 to 800	32	0
801 to 1,000	33	0
1,001 to 100,000	55	1

(8) Lot Tolerance Percent Defective 10.0 percent:

Lot size	Sample size	Acceptance No.
1 to 20	All	0
21 to 50	17	0
51 to 100	20	0
101 to 200	22	0
201 to 800	23	0
801 to 100,000	39	1

[39 FR 22130, June 20, 1974]

Subpart D—Specifically Licensed Items

§ 32.210 Registration of product information.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to NRC

for evaluation of radiation safety information about its product and for its registration.

(b) The request for review must be sent to the NRC's Office of Nuclear Material Safety and Safeguards, Materials Safety and Inspection Branch, by an appropriate method listed in §30.6(a) of this chapter.

(c) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(d) The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

(f) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with—

(1) The statements and representations, including quality control program, contained in the request; and

(2) The provisions of the registration certificate.

[52 FR 27786, July 24, 1987, as amended at 60 FR 24551, May 9, 1995; 68 FR 58805, Oct. 10, 2003]

Subpart E—Violations

§ 32.301 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55073, Nov. 24, 1992]

§ 32.303 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 32 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 32 that are not issued under subsections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 32.1, 32.2, 32.8, 32.11, 32.14, 32.17, 32.18, 32.22, 32.23, 32.24, 32.26, 32.27, 32.28, 32.51, 32.53, 32.57, 32.61, 32.71, 32.74, 32.301, and 32.303.

[57 FR 55073, Nov. 24, 1992, as amended at 59 FR 61781, Dec. 2, 1994]